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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/647,475 | 08/20/2001 | Olav K. Lyngberg | 110.00810101 | 7111 |

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EXAMINER

CHEU, CHANGHWA J *H*

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1641 | |

DATE MAILED: 03/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|-----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/647,475 | LYNGBERG ET AL. |
| | Examiner | Art Unit |
| | Jacob Cheu | 1641 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 February 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-99 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____ .
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . 6) Other: _____ .

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-24 and 48, drawn to a composite biological device, comprising the “special technical feature” of at least a portion of the biostructure comprises a nonporous latex-derived material.

Group II, claim(s) 25 and 26, drawn to a composite biological device, comprising the “special technical feature” of a 3-dimensional porous latex biostructure and disposed on a porous substrate.

Group III, claim(s) 27-30, drawn to a method of making a composite biological device.

Group IV, claim(s) 31-47 and 49, drawn to a composite biological device, comprising the “special technical feature” of determining the presence of metal in a sample and emitting a signal upon in contact with the metal.

Group V, claim(s) 50-82, drawn to a microstructure device, comprising the “special technical feature” of the interior volume configured to accept a sample to determine if the sample contains analyte material that will elicit a detectable response.

Group VI, claim(s) 83-93, drawn to a test device, comprising the “special technical feature” of having a housing configured to sufficiently penetrate a solid object.

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Group VII, claim(s) 94-99, drawn to a test system, comprising the “special technical feature” of having a microporous polymeric matrix and entrapping the immobilized cells within voids present within the matrix.

2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I recites a composite biological device comprising at least one metabolically active biological material as an integral component and at least a portion of the biostructure comprising a nonporous latex-derived material. However, such device is not novel, and in fact can be read on by the over-the-counter nonporous latex condom. For instance, the spermicide is widely used in commercially available condom. In order to test the efficacy of variety of spermicides, sperms cells, i.e. metabolically active, are put into condom coated with spermicide, and subsequently conduct cell viability assay. Therefore, the invention of group I does not fulfill the requirement for unity of invention under Rule 13.1 PCT. Accordingly, the different method of making the device in group III is not so linked as to form a single general inventive concept.

3. As set forth above, each product of group I, II, IV-VII, has special technical feature not shared by the other groups. Therefore, the invention listed as groups I, II, IV-VII do not relate to a single general inventive concept because the lack of the same corresponding technical feature.

4. Restriction is required under 35 U.S.C. 121 and 372. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu *Jacob Cheu*
Examiner

Art Unit 1641

March 13, 2003

Long V. Le
LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
03/14/03